

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)) MDL No. 16-2740
PRODUCTS LIABILITY)
LITIGATION) SECTION: “H” (5)
)
This document relates to:)
June Phillips, No. 16-15397)

ORDER AND REASONS

Before the Court is a Motion for Summary Judgment on Warnings Causation (Doc. 9299). The Court held oral argument on the Motion on March 11, 2020. For the following reasons, the Motion is **GRANTED**.

BACKGROUND

Plaintiffs in this multidistrict litigation (“MDL”) are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,¹ that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more.

In the instant Motion, Defendants argue that Plaintiff June Phillips cannot establish the essential element of causation in her case. Defendants therefore ask the Court to grant summary judgment in their favor.

¹ Docetaxel is the generic version of Taxotere.

LEGAL STANDARD

Summary judgment is warranted where “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”² A genuine issue of fact exists only “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.”³ When considering a summary judgment motion, the Court must view the entire record in the light most favorable to the non-moving party and indulge all reasonable inferences in that party’s favor.⁴

LAW AND ANALYSIS

Defendants first argue that they had no duty to warn Plaintiff’s treating physician, Dr. Scott Sonnier. Defendants aver that when Dr. Sonnier treated Plaintiff in 2013, he knew of the risk of permanent hair loss associated with Taxotere. Because Dr. Sonnier had knowledge of the risk, Defendants say they were relieved of their duty to warn him. According to Defendants, Dr. Sonnier’s practice at the time he treated Plaintiff Phillips was to discuss the risk of permanent hair loss with his patients. Defendants further aver that Plaintiff cannot show causation because Dr. Sonnier testified that even with the knowledge he has today, he still believes that Phillips needed a Taxotere-containing regimen—specifically, the “TCH” regimen.⁵ Defendants note that there is no evidence showing that Plaintiff inquired about other options.

² FED. R. CIV. P. 56.

³ *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

⁴ *Crawford v. Formosa Plastics Corp.*, 234 F.3d 899, 902 (5th Cir. 2000).

⁵ The TCH regimen contains Taxotere, Carboplatin, and Herceptin.

Lastly, Defendants emphasize that Dr. Sonnier testified that no other options were suitable for treating Phillips' aggressive cancer.

In response, Plaintiff notes that Dr. Sonnier unequivocally testified that the 2015 label change altered the disclosures he makes to his patients. Specifically, he testified that he now tells patients that there can be permanent hair loss from Taxotere. Based on this, Plaintiff argues that before the label change Dr. Sonnier was not warning patients as Defendants suggest—according to Plaintiff, Dr. Sonnier would not have warned patients based only on lay reports of permanent alopecia. Instead, before the label change, Dr. Sonnier gave patients only a warning about chemotherapy in general, and he told them that their hair loss would likely be temporary.

Plaintiff further disputes that Dr. Sonnier would have recommended Taxotere to Plaintiff even knowing what he knows today. According to Plaintiff, Dr. Sonnier could have recommended alternative treatments. Plaintiff emphasizes that she would have changed her decision to take Taxotere if she had been warned of its risk of permanent hair loss.

Under Louisiana law, failure to warn claims involving prescription drugs are subject to the learned intermediary doctrine.⁶ Under the doctrine, the manufacturer of a prescription drug “has no duty to warn the patient, but need only warn the patient’s physician.”⁷ In other words, a manufacturer’s duty runs only to the physician—the learned intermediary.⁸

The Fifth Circuit has held that there is a two-prong test governing inadequate warning claims under the Louisiana Products Liability Act (LPLA) when the learned intermediary doctrine is applicable:

⁶ *Grenier v. Med. Eng’g Corp.*, 99 F. Supp. 2d 759, 765 (W.D. La. 2000) (applying Louisiana law), *aff’d*, 243 F.3d 200 (5th Cir. 2001).

⁷ *Willett v. Baxter Intern., Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991).

⁸ *Grenier*, 99 F. Supp. 2d at 766.

First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury.⁹

Regarding the second prong, the law is well established that, to prove causation, "the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product."¹⁰

As the Court has discussed in prior rulings, the chemotherapy decision-making process is unique. The Court must consider not only whether an oncologist would have warned his or her patient of the risk of permanent alopecia but also how patient choice then would have steered the conversation and the ultimate prescribing decision.

Defendants have pointed to sufficient evidence showing that Plaintiff cannot establish causation. Dr. Sonnier testified that there were no adequate alternative options for Plaintiff Phillips, who had an aggressive cancer.¹¹ Although Dr. Sonnier identified "AC followed by Taxol" and "TAC" as alternative options to TCH, both of these alternative regimens include Adriamycin, which "is a cardio toxic agent" that Dr. Sonnier "wanted to avoid specifically in [Phillips] case."¹² He testified as follows:

⁹ *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 265–66 (5th Cir. 2002) (internal citation omitted).

¹⁰ *Willett*, 929 F.2d at 1099. *See also* *Pellegrin v. C.R. Bard*, 2018 WL 3046570, at *4 (E.D. La. June 20, 2018).

¹¹ Phillips had a HER2+ cancer.

¹² Doc. 9299-5 (p. 35). (Doxorubicin is another name for Adriamycin.)

Q: [I]n her situation, what were the other alternative treatments?

A: There's a regimen called AC followed by Taxol. A regimen called TAC: Taxotere, Adriamycin, and Cyclophosphamide.

Then kind of getting to – so with her having lymph node positive disease and there's a high risk of recurrence, you would tend to favor giving the three active medications that we use for adjuvant treatment.

Prior to this regimen of TCH, which had just been approved, there was, generally, the three were Cyclophosphamide, Taxotere, I should say a taxane, which is Taxol or Taxotere, and Adriamycin.

So just prior to the approval of TCH, there was no regimen that did not contain an anthracycline, which is a cardio toxic medication. With the recent passage of the TCH protocol, we avoided the anthracycline use.

[. . .]

Q: At the time that you recommended Taxotere, if Ms. Phillips had said, "Look, I don't want to go forward with the Taxotere regimen because," if you had known of the risk of permanent hair loss, "I don't want to go forward with that risk. I'm willing to go forward with AC plus the Taxol," would you have allowed her to go forward with that treatment as your patient?

[. . .]

A: We would have a serious discussion about the risk of cardiac toxicity. And I, I don't know if I included in my note here, but I'm fairly certain – again, I kind of remember some cases at that

initial conversation. And part of the discussion was the alternative of anthracycline-based therapies, and the serious concern we had about the cardiac toxicity.¹³

Dr. Sonnier testified that cardio toxicities are increased in a person over the age of 65, and Phillips was 75 at the time of her treatment.¹⁴ Dr. Sonnier further testified that Phillips had a preexisting cardiac condition known as paroxysmal atrial tachycardia.¹⁵ This condition “would have been more of a caution,” and this is part of the reason he recommended TCH for Phillips.¹⁶

When asked if the client makes the ultimate decision about which chemotherapy regimen to use, Dr. Sonnier responded as follows: “I wouldn’t say that. Because had [Phillips] come in and said, ‘I want Adriamycin as my regimen,’ I would say, ‘I think that’s a very risky proposal,’ and that I would not give it.”¹⁷ Indeed, in the guidelines issued by the National Comprehensive Cancer Network (“NCCN”) in 2013, the TCH regimen is described as a “preferred regimen, especially in those with risk factors for cardiac toxicity.”¹⁸ Dr. Sonnier testified that he followed the NCCN guidelines.¹⁹

Considering this evidence, Defendants have demonstrated that even with an adequate warning from Sanofi, Plaintiff and Dr. Sonnier would have decided on a Taxotere regimen to treat her cancer. Plaintiff has failed to rebut this. Plaintiff has pointed to no evidence suggesting that she would have looked for another oncologist. Indeed, the evidence suggests that she never inquired about other options but instead trusted Dr. Sonnier and heeded his advice.

¹³ *Id.* (p. 36–37).

¹⁴ *Id.* (p. 65).

¹⁵ *Id.* (p. 65–66).

¹⁶ *Id.* (p. 66).

¹⁷ *Id.* (p. 98).

¹⁸ Doc. 9229-8.

¹⁹ Doc. 9299-5 (p. 13–14).

CONCLUSION

Accordingly, for the foregoing reasons, the Motion for Summary Judgment on Warnings Causation (Doc. 9299) is **GRANTED**.

New Orleans, Louisiana this 7th day of April, 2020.

A handwritten signature in black ink, appearing to read "Jane Triche Milazzo", written over a horizontal line.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE